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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/391,606	09/07/99	MURDIN A	1038-971-MIS

HM22/0605

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EXAMINER	
PENN, M	
ART UNIT	PAPER NUMBER
1633	13

DATE MAILED: 06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/391,606	MURDIN ET AL.	
	Examiner	Art Unit	
	Michael Penn	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michael G. Penn, Art Unit 1633.

Claims 1-23 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, SEQ ID's 13 and 3 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that there is no undue burden to search all sixteen of the sequences because all of the sequences relate to two gene sequences *of C. pneumoniae*. This is not found persuasive because each sequence is searched individually, not as a group, and therefore the search burden remains. Claims 3 and 8 are withdrawn as directed to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

Claims 1,2, 4-7, and 9-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Although enabled for administration of a plasmid vector encoding a chlamydia MOMP protein and a chlamydia 76kDa protein, and induction of a protective immune response against chlamydial infection in mice, the specification does not reasonably provide enablement for the use of all types of vector systems. Nor does the specification reasonably provide enablement for the induction of a protective immune response in all hosts, including humans. A protective vaccine against chlamydia for mice would not constitute a patentable substantial utility. The nature of the invention as claimed is a DNA vaccination. This art lies within the realm of gene therapy, specifically, *in vivo* gene transfer.

While progress has been made in recent years related to in vivo gene transfer, the field of in vivo gene transfer at the time of the instant application, and currently, remains highly unpredictable as exemplified in Anderson's review of the state of the art of gene therapy (Anderson, Nature, April 30, 1998, pp. 25-30). This unpredictability can be attributed to several factors including "...poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered...[because]...we still lack a basic understanding of how vectors should be constructed, what regulatory sequences are appropriate for which cell types, [and] how *in vivo* immune defenses can be overcome..." (Anderson, p. 30).

Furthermore, with regard to extrapolation from mouse models to man, the state of the art exemplified by McCluskie et al. (Mol. Med., 5, pp. 287-300, 1999) teaches that "the realization that results in mice often do not predict the situation in humans has also led to a large number of DNA vaccine studies in non-human

primates," that "IM injection of plasmid DNA vaccines, while highly immunogenic in mice...was found only to be relatively so in chimpanzees..., and especially not at all in Aotus monkeys" and that "it is probably safe to say that any vaccine that works in a human will work in a mouse, but not necessarily vice-versa" (p. 296, column 2, second and third paragraphs). In addition, McCluskie et al. teaches that "although non-human primate models are frequently used for development and testing of human vaccines, it is not clear how predictive they will be in the case of DNA vaccines where efficacy, by virtue of the requirement to transfect cells and express the antigen, relies on many factors other than immunological responses to the antigen" (p. 297, column 1). Thus it is not apparent how one skilled in the art reasonably extrapolates, without undue experimentation, from the mouse model described in the specification to the full scope of the claimed invention.

Moreover, Stagg et al. (Stagg et al., Mol. Med. Today, April 1998, pp. 166-173) teaches in his review of *Chlamydia* vaccines that "...the immune response to *Chlamydia* is both complex and flexible... [and that] ...it is not yet clear which is the most appropriate response to target for immunoprophylaxis, or whether it will be possible to confer protection while avoiding immunopathology. Much of our understanding of cell-mediated immunity in chlamydial infection is based upon mouse models; little is known about the response in humans. Given that the infection in humans runs a chronic course and appears to produce only short-term, serovar-specific immunity, the possibility that the organism has evolved mechanisms to block or evade the protective mechanisms that have been identified in mice warrants further investigation." (p. 169,

under Exploiting the immune response to Chlamydia). Accordingly, the state of the art regarding Chlamydia vaccines at the time of the instant application was highly unpredictable.

The mechanisms involved in the immune response vary greatly depending upon the antigen at issue. One skilled in the art would have recognized that the results obtained in the mouse model as described are not necessarily predictive of the outcome in other species of animals, including humans, particularly in light of the teachings of Stagg. Thus, it is not apparent how one skilled in the art extrapolates, without undue experimentation, from the mouse model to the full scope of the claimed invention. Therefore, considering the unpredictability of the art of *in vivo* gene delivery, the limited guidance provided in the specification, the broad scope of the claims, the limited scope of working examples and lack of enabling data, it would have required one of skill in the art at the time of filing undue experimentation to make and/or use the claimed invention.

No claims are allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Penn who can normally be reached on Monday through Friday from 8:00 am to 4:30 p.m. at (703) 308-2454.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, who can normally be reached on Monday through Friday from 9:00 am to 5:30 p.m. at (703) 305-3015.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael G. Penn

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